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(Original Signature of Member)

118TH CONGRESS
2D SESSION

H. R. _____

To direct the Secretary of Health and Human Services to enter into agreements with drug manufacturers to establish reserve supplies of covered pediatric cancer drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. ESHOO introduced the following bill; which was referred to the Committee on _____

A BILL

To direct the Secretary of Health and Human Services to enter into agreements with drug manufacturers to establish reserve supplies of covered pediatric cancer drugs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SEC. 1. SHORT TITLE.

This Act may be cited as the ''Pediatric Cancer Drug Supply Act of 2024''.

SEC. 2. ESTABLISHMENT OF ESSENTIAL PEDIATRIC CANCER DRUG MARKETPLACE STABILITY PILOT PROGRAM.

(a) IN GENERAL.—The Secretary shall carry out a pilot program under which the Secretary enters into agreements with manufacturers to purchase and maintain not less than a 6-month reserve supply, to be held by such manufacturers, of each covered pediatric cancer drug.

(b) PILOT PROGRAM.—

(1) PREFERENCE FOR MULTIPLE MANUFACTURERS.—To the greatest extent practicable, the Secretary shall seek to enter into agreements described in subsection (a) with more than 1 manufacturer for each covered pediatric cancer drug.

(2) IMPLEMENTATION GOALS.—To the greatest extent practicable, the Secretary shall implement the pilot program under this section in a manner that—

(A) minimizes the impact on the marketplace for drugs included on the essential pediatric cancer drug list established under section 3;

(B) increases domestic manufacturing capacity;

(C) encourages competition in the marketplace;

(D) assures that any covered pediatric cancer drugs that the Secretary distributes or orders to be distributed under section 4 are used to treat pediatric cancer patients; and

(E) rewards manufacturing quality.

(3) REQUIRED AGREEMENT TERMS.—Each agreement under this section between the Secretary and a manufacturer of a covered pediatric cancer drug shall include the following:

(A) The identity and quantity of each covered pediatric cancer drug that the manufacturer agrees to hold in reserve supply.

(B) A requirement that such quantities shall be in addition to the average levels of inventory for the relevant covered pediatric cancer drug held by the manufacturer during the previous year.

(C) A provision to ensure that each drug held in reserve supply has an expiration date at least 1 year beyond the current date.

(D) A provision to allow the manufacturer to sell and replace, through normal commercial channels, any drug in reserve supply in order to remain in compliance with the provision described in subparagraph (C).

(E) A requirement that the covered pediatric cancer drugs in reserve supply may only be held at a location in the United States.

(F) In the case of a covered pediatric cancer drug manufactured at an eligible source facility that is not located in the United States, the manufacturer of such drug may comply with subparagraph (E)—

(i) by storing the drug at an establishment located in the United States that is—

(I) registered under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360); and

(II) under common ownership and control with the manufacturer; or

(ii) by contracting with an authorized third-party logistics provider (as defined in section 581 of the Federal Food Drug, and Cosmetic Act (21 U.S.C. 360eee)) located in the United States to store the drug in the United States.

(G) A requirement that any covered pediatric cancer drug held in reserve supply be manufactured and held in accordance with—

(i) good manufacturing practice requirements;

(ii) the approved application for such drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262); and

(iii) applicable law.

(H) A provision that allows the Secretary, or a third party designated by the Secretary, to audit the manufacturer and the eligible source facility for compliance with the terms of the agreement and applicable law—

(i) on an annual basis; or

(ii) more frequently, if the Secretary has a reasonable basis to believe that the manufacturer or eligible source facility is not complying with the terms of the agreement or applicable law.

(I) A requirement that the manufacturer certify to the Secretary on an annual basis compliance with the terms of the agreement.

(4) OPTIONAL TERMS FOR ACQUISITION, CONSTRUCTION, ALTERATION, OR RENOVATION OF ESTABLISHMENT.—An agreement under this section

between the Secretary and a manufacturer of a covered pediatric cancer drug may include a provision to allow the manufacturer to acquire, construct, alter, or renovate a non-federally owned establishment for the purpose of manufacturing covered pediatric cancer drugs—

(A) as the Secretary determines necessary to ensure sufficient amounts of such drugs; or

(B) as the Secretary determines necessary to carry out or improve preparedness and response capability at the State and local levels.

(5) REASONABLE TIME FOR MANUFACTURE.—The Secretary shall allow each manufacturer with whom the Secretary has entered into an agreement under this section a reasonable amount of time after entering into the agreement to manufacture the covered pediatric cancer drugs that will be held in reserve supply pursuant to the agreement.

(c) PAYMENT TERMS.—

(1) PAYMENT AMOUNTS.—

(A) IN GENERAL.—The amount paid to each manufacturer pursuant to an agreement with the Secretary under this section shall be based on—

(i) the quantity of each covered pediatric cancer drug the manufacturer agrees to hold in reserve supply; and

(ii) the wholesale acquisition cost of each such drug.

(B) ADMINISTRATIVE FEE.—The Secretary may pay a manufacturer an administrative fee pursuant to an agreement under this section, provided that the payment of the administrative fee does not cause the Secretary to exhaust the amounts appropriated for the pilot program under this section prior to securing adequate reserves for each covered pediatric cancer drug.

(2) PAYMENT CONDITIONED ON RESERVE SUPPLY ADEQUACY.—

(A) IN GENERAL.—Except as provided in subparagraph (B), each agreement with a manufacturer under this section shall provide that no payment under the agreement may be made until the manufacturer demonstrates to the Secretary that the manufacturer has set aside a portion, as determined by the Secretary, of the total quantity of the covered pediatric cancer drug to be held in reserve supply under the agreement.

(B) EXCEPTIONS FOR ADVANCE PAYMENT.—An agreement under this section may provide that, if the Secretary determines that an advance payment or partial payment for significant milestones is necessary to ensure success of the terms of the agreement, the Secretary shall pay, in advance, an amount not to exceed 10 percent of the total amount to be paid to the manufacturer by the Secretary under the agreement.

(d) FORFEITURE.—If a manufacturer is unable or fails to distribute a covered pediatric cancer drug in accordance with the terms of an agreement entered into under this section, the manufacturer shall—

(1) forfeit any payments it has received under the agreement; and

(2) not later than 30 days after the date of such inability or failure, refund such payments.

SECTION 3. ESSENTIAL PEDIATRIC CANCER DRUG LIST.

(a) IN GENERAL.—The Secretary, in consultation with the Commissioner of Food and Drugs and the Director of the National Cancer Institute, shall—

(1) not later than 150 days after the date of enactment of this Act, develop a list of

chemotherapeutic drugs that are essential for treating pediatric cancer; and

(2) update such list on a schedule determined by the Secretary.

(b) CRITERIA.—Under subsection (a), a chemotherapeutic drug shall be considered essential for treating pediatric cancer only if the drug—

(1) is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) for use in the treatment of cancer;

(2) has the potential alone or in combination with other drugs to treat a pediatric cancer;

(3) is supported by 1 or more citations to treat a pediatric cancer included or approved for inclusion in—

(A) the National Comprehensive Cancer Network Compendia;

(B) American Hospital Formulary Service Drug Information;

(C) the DRUGDEX Information System; or

(D) the PDQ Cancer Information Summaries for Health Professionals of the National Cancer Institute; and

(4) meets price, quality, manufacturing concentration, manufacturing complexity, and other appropriate metrics as determined by the Secretary.

SEC. 4. DISTRIBUTIONS FROM ESSENTIAL PEDIATRIC CANCER DRUG RESERVE SUPPLIES.

(a) IN GENERAL.—If a covered pediatric cancer drug is in shortage (as defined in section 506C(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(h))), or the Secretary has reason to believe that such a drug may be at risk of such a shortage, the Secretary may order a manufacturer with whom the Secretary has entered into an agreement under section 2 to distribute such drug from the reserve supply in accordance with such agreement in an effort to alleviate or prevent the shortage.

(b) PAYMENTS FOR DISTRIBUTION.—

(1) IN GENERAL.—The Secretary shall require a recipient of a covered pediatric cancer drug distributed under subsection (a) to pay the Secretary for such drug. The amount of such payment shall not exceed the price for which the Secretary purchased such drug pursuant to an agreement under section 2.

(2) LIMITATION.—The Secretary may use payments received pursuant to paragraph (1) only to replenish the reserve supply of the drugs distributed under subsection (a).

(c) INABILITY TO DISTRIBUTE OR MANAGE RESERVE SUPPLY.—

(1) INABILITY TO DISTRIBUTE.—If a manufacturer is not able or willing to distribute drugs in accordance with an order of the Secretary under subsection (a), the Secretary may take possession of and distribute such drugs.

(2) INABILITY TO MANAGE RESERVE SUPPLY.—If a manufacturer can no longer hold or manage a reserve supply of covered pediatric cancer drugs in accordance with an agreement under section 2, the Secretary may take possession of the reserve supply.

SEC. 5. REPORTS TO CONGRESS.

(a) IN GENERAL.—For each year 1 or more drugs are held by a manufacturer in reserve supply pursuant to an agreement under section 2, the Secretary shall submit to Congress a report on the progress of the pilot program under such section.

(b) CONTENTS.—The reports referred to in subsection (a) shall each include—

(1) the essential pediatric cancer drug list in effect during the year covered by the report (including any changes made to the list throughout the year);

(2) the total number of agreements entered into under section 2 during such year;

(3) the total amount of each covered pediatric cancer drug purchased by the Secretary pursuant to such agreements during such year;

(4) the total amount of each covered pediatric cancer drug distributed from the reserve supplies under section 4 during such year; and

(5) any other information that the Secretary determines relevant.

SEC. 6. DEFINITIONS.

In this Act:

(1) COVERED PEDIATRIC CANCER DRUG.—The term ''covered pediatric cancer drug'' means a drug—

(A) that is included on the essential pediatric cancer drug list established under section 3;

(B) that may be at risk of a meaningful disruption (as defined in section 506J(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356j(j))) in the supply of the drug; and

(C) whose final dosage form is manufactured at an eligible source facility.

(2) DRUG.—The term ''drug''—

(A) means a drug (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g))); and

(B) includes a biological product (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i))).

(3) ELIGIBLE SOURCE FACILITY.—The term ''eligible source facility'' means a facility—

(A) registered under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360);

(B) lawfully manufacturing a covered pediatric cancer drug; and

(C) located in—

(i) the United States; or

(ii) a country that is a member of the Organisation for Economic Co-operation and Development.

(4) ESSENTIAL PEDIATRIC CANCER DRUG LIST.—The term ''essential pediatric cancer drug list'' means the list under section 3(a).

(5) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(6) UNITED STATES.—The term ''United States'' means each of the several States and the territories and possessions of the United States.

SEC. 7. AUTHORIZATION OF APPROPRIATIONS.

To carry out this Act, there are authorized to be appropriated $500,000,000 for fiscal year 2024, to remain available until expended.